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Attorney's Docket No.: 17111-007US1/2307US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : James Keck et al.
Serial No. : 09/601,997
Filed : December 15, 2000
Cust. No. : 20985
Title : NON-BACTERIAL CLONING IN DELIVERY AND EXPRESSION OF
NUCLEIC ACIDS

Art Unit : 1633
Examiner : Janet L. Epps-Ford
Conf. No. : 5984

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are a Request For Reconsideration Of Petition Under 37 C.F.R. §1.181 For Withdrawal Of The Finality Of The Office Action and a return postcard in connection with the above-captioned patent application. No fee should be due. However, if it is determined that a fee is due, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050 for the appropriate fee as stated below. If a Petition for extension of time is needed, this paper is to be considered such Petition.



The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

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Attorney Docket No. 17111-007US1/2307US

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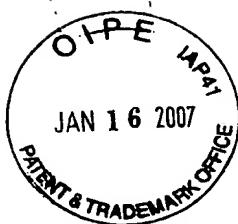
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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman



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**REQUEST FOR RECONSIDERATION OF PETITION UNDER 37 C.F.R. §1.181 FOR
WITHDRAWAL OF THE FINALITY OF THE OFFICE ACTION**

Dear Sir:

Applicant hereby requests reconsideration of the *PETITION DECISION* mailed December 20, 2006, in connection with the above-captioned application. Applicant submitted a *PETITION UNDER 37 C.F.R. §1.181* (hereinafter, "Petition") on October 30, 2006, requesting reconsideration and removal of the finality of the Office Action mailed October 18, 2006 (hereinafter, "Office Action").

The Petition was granted in part, to the extent that the Office Action was withdrawn and the application returned to the Examiner for preparation of a new Office Action. In the Petition Decision, the Director states that the Office Action is withdrawn as incomplete because the Examiner improperly "declined to apply a prior art rejection . . . until the ambiguities in the claims were resolved."

The Petition however was denied in part because it is alleged that, contrary to Applicant's assertion, the finality of the Office Action is proper. Specifically, the Director states that in the Office Action, there was no new ground of rejection and the Examiner "merely expanded on the [previous] rationale for finding said claims indefinite." Applicant respectfully disagrees.

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Stephanie Seidman

In the Petition filed October 30, 2006, Applicant argued, among others, the following new grounds of rejection as exemplary of the finality of the Office Action being improper:

(1) The Examiner alleges that claim 58 and its dependents are incomplete because there is no mention of a control, untransfected host cell for comparison with the transfected cell when analyzing changes in phenotype in the transfected cell.

(2) The Examiner alleges that claim 58 and its dependents are incomplete because the recitation "antisense strand that, when expressed as RNA, binds to an mRNA transcribed from the target nucleic acid sequence," allegedly suggests that the antisense RNA produced from the sense strand of the double-stranded DNA targets an mRNA other than the mRNA coded for by a sample nucleic acid sequence in the target nucleic acid molecule, as set forth in the preamble.

In the Petition Decision, the Director provides reasons why (2) above allegedly is not a new ground of rejection, which Applicant has addressed further below. Applicant however respectfully submits that the Petition Decision fails to address the new ground of rejection (1) pointed to by Applicant in the Petition and set forth above, namely, the allegation that the claims are incomplete because there is no mention of comparing transfected host cells to a control.

(1) REJECTION THAT THERE IS NO MENTION OF A "CONTROL, UNTRANSFECTED HOST CELL" FOR ANALYZING CHANGES IN PHENOTYPE.

In the final Office Action mailed October 18, 2006, the Examiner alleges that claim 58 as a whole and its dependents are incomplete because there is no mention of a control, untransfected host cell for comparison with the transfected cell when analyzing changes in phenotype in the transfected cell.

Applicant respectfully submits that the above ground of rejection of Claim 58 and dependents could have been applied in the previous Office Action mailed October 20, 2005, or indeed in any one of several non-final earlier Office Actions that issued in connection with the above-captioned application including, for example, the Office Action mailed January 9, 2003, the Office Action mailed April 20, 2004, and the Office Action mailed February 3, 2005. As discussed in the Petition mailed October 30, 2006, and herein, the claims never mentioned a control, and have never been rejected on this basis. Hence the assertion that the claims fail to recite a control is a new ground of rejection not necessitated by amendment of the claims.

**(A) Claim 58 as pending at the time the previous Office Action was mailed
(October 20, 2005)**

For example, at the time that the previous Office was mailed (October 20, 2005), Claim 58 recited:

A high-throughput method of assigning a function associated with a product coded for by a sample nucleic acid sequence in a target nucleic acid molecule, said method comprising:

a) without any intervening bacterial cloning steps and without any conformational modeling of mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence, delivering into and amplifying and expressing a plurality of members of an oligonucleotide family as individual transcription products in a plurality of recombinant non-bacterial host cells comprising the target nucleic acid molecule that comprises the sample nucleic acid sequence, whereby the method is high-throughput, wherein:

the members of the oligonucleotide family comprise a plurality of nucleic acids each encoding a transcription product comprising a sequence that is complementary to a sequence contained in the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence;

the plurality of members of the oligonucleotide family are introduced into expression vectors, which are introduced into the host cells, wherein the expression vectors comprise:

double-stranded DNA, comprising:

a sense strand and an antisense strand, wherein the sense strand codes for an antisense strand that, when expressed as RNA, binds to an mRNA sequence transcribed from the target nucleic acid sequence so that expression of a product from the target nucleic acid is inhibited; and

means for determining directionality of expression, wherein the product is associated with at least one phenotypic property of a host cell containing the mRNA sequence; and wherein the expression vector is for expression in non-bacterial host cells;

the coding sequences for each individual transcription product encodes an antisense nucleic acid that, when expressed as RNA, binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence; and

expression of one or more of the individual transcription products inhibits production of a product of the mRNA; and

b) in the resulting host cells, analyzing changes in phenotype to thereby assign a function associated with the product encoded by the sample nucleic acid sequence in the target nucleic acid molecule. (emphasis added).

(B) Claim 58 as pending at the time the instant final Office Action was mailed (October 18, 2006) (amended portions responsive to previous Office Action of October 20, 2005, indicated in underline (additions) and strikeout (deletions))

Claim 58 as presently pending recites:

A high-throughput method of assigning a function associated with a product coded for by a sample nucleic acid sequence in a target nucleic acid molecule, said method comprising:

a) without any intervening bacterial cloning steps and without any conformational modeling of mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence, delivering into and amplifying and expressing a plurality of members of an oligonucleotide family as individual transcription products in a plurality of recombinant non-bacterial host cells comprising the target nucleic acid molecule that comprises the sample nucleic acid sequence, whereby the method is high-throughput, wherein:

the plurality of members of the oligonucleotide family are introduced into expression vectors, which are introduced into the host cells, wherein the expression vectors comprise:

double-stranded DNA, comprising:

a sense strand and an antisense strand, wherein the sense strand codes for an antisense strand that, when expressed as RNA, binds to an mRNA sequence transcribed from the target nucleic acid sequence so that expression of a product from the target nucleic acid is inhibited; and

means for determining directionality of expression, wherein the product is associated with at least one phenotypic property of a host cell containing the mRNA sequence; and wherein the expression vector is for expression in non-bacterial host cells;

the coding sequences sequence for each individual transcription product encodes an antisense nucleic acid that[[,]] when expressed as RNA, binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence; and

expression of one or more of the individual transcription products inhibits production of a product of the mRNA; and

b) in the resulting host cells, analyzing changes in phenotype to thereby assign a function associated with the product encoded by the sample nucleic acid sequence in the target nucleic acid molecule. (emphasis added)

As the emphasized (bold) sections of Claim 58 as recited in (A) and (B) above show, the step of analyzing changes in phenotype has not been amended responsive to the previous Office

Action. In fact, at no point during prosecution of this application was the above phrase “analyzing changes in phenotype” (in the transfected host cells produced by the method) amended responsive to an Office Action and/or rejections cited therein. Therefore, the rejection that the claims are indefinite for failing to recite a control could have been applied in the previous Office Action mailed October 20, 2005, or indeed in any of the Office Actions that have issued in this case. The claims however have never been rejected on this basis prior to the instant final Office Action mailed October 18, 2006.

Because the step of “analyzing changes in phenotype” was not amended responsive to the previous Office Action, and in fact has always been recited as such without mention of a control, therefore the rejection of indefiniteness for failing to recite a control was not necessitated by amendment and could have been applied in the previous Office Action or in any one of a number of Office Actions prior to the instant Final Office Action. Applicant therefore respectfully submits that the basis of indefiniteness for failure to recite a control is a new ground of rejection that renders the finality of the instant Office Action improper.

(2) REJECTION THAT THE RECITATION “ANTISENSE STRAND THAT, WHEN EXPRESSED AS RNA, BINDS TO AN mRNA TRANSCRIBED FROM THE TARGET NUCLEIC ACID SEQUENCE” (LINES 15-16), ALLEGEDLY SUGGESTS THAT THE ANTISENSE RNA PRODUCED FROM THE SENSE STRAND TARGETS AN mRNA OTHER THAN THE mRNA “CODED FOR BY A SAMPLE NUCLEIC ACID IN THE TARGET NUCLEIC ACID”

With respect to rejection (2) that was exemplified by Applicant as a new ground of rejection not necessitated by amendment, the Petition Decision states that there is no new ground of rejection because the phrase that formed the basis of the rejection in the previous and instant Office Actions is the same. Specifically, the Director states that the phrase “antisense strand that, when expressed as RNA, binds to an mRNA transcribed from the target nucleic acid sequence,” formed the basis of the rejection in the previous Office Action mailed October 20, 2005, and the Examiner merely expanded on this basis in the instant final Office Action. Applicant respectfully submits that although the aforementioned phrase was cited as the basis for rejecting the claims in the previous and instant Office Actions, the grounds are not the same.

Claim 58 as pending at the time the previous Office Action was mailed (October 20, 2005) recited the phrase, “antisense strand that, when expressed as RNA, binds to an mRNA

transcribed from the target nucleic acid sequence," two times (*see* Claim 58 under (A) above):

- (a) the phrase characterized the element "each individual transcription product," which refers to each antisense RNA encoded by a member of the oligonucleotide family; and
- (b) the phrase characterized the element "expression vectors," which are a plurality of cloned double stranded DNA molecules into which the family of oligonucleotides encoding a plurality of antisense RNA are introduced.

The basis for the rejection on grounds of indefiniteness applied to the nature of "each individual transcription product" and not to the expression vectors. As the Office Action of October 20, 2005, alleged:

The metes and bounds of the claimed method are vague and indefinite because **the nature of the transcription product is vague and indefinite** It is the examiner's understanding that **the transcription product** that comprises a sequence that is complementary to the mRNA transcribed from the target nucleic acid molecule, is already "antisense" to the mRNA transcribed from the target nucleic acid molecule It is unclear if the claim[s] encompass an additional antisense molecule (see lines 15-18) (emphasis added).

In response, Applicant amended the claims to clarify that "each individual transcription product" is an RNA molecule that is antisense to the mRNA transcribed from the target nucleic acid, and there are no additional antisense molecules. The phrase, "antisense strand that, when expressed as RNA, binds to an mRNA transcribed from the target nucleic acid sequence," as it characterized the term "each individual transcription product," was deleted.

The phrase as it characterized the term "expression vectors" however was retained because, as noted above, the "expression vectors" contain a family of double-stranded DNA molecules encoding more than one antisense molecule whose sequence is complementary to mRNA transcribed from the target nucleic acid molecule (*see* Claim 58 under (B) above, marking amendments responsive to the Office Action of October 20, 2005).

In the instant final Office Action, the Examiner now asserts that the claims remain indefinite because it allegedly is unclear whether the "cloned double stranded DNA" (of which the expression vectors are comprised) encode transcription products that bind to an mRNA other than an mRNA product transcribed from the sample nucleic acid sequence in the target molecule. Therefore, the instant rejection is not merely an expansion of the previous rejection, but a new

ground of rejection, namely, alleged indefiniteness of the term "expression vectors" rather than the term "each individual transcription product."

Failure to withdraw the finality of the instant Office Action denies the Applicant the right to amend the claims, if needed, and/or provide arguments to overcome these rejections, not previously of record during the prosecution of this application. **For example, prior to the instant final Office Action, Applicant has never been granted the opportunity to address the alleged indefiniteness of the claims because the step of "analyzing phenotypic changes" must (allegedly) recite a comparison against a control.** Applicant therefore respectfully requests reconsideration of the Petition Decision and grant of Applicant's Petition requesting removal of the finality of the Office Action mailed October 18, 2006.

* * *

In light of the above remarks and the Petition mailed October 30, 2006, reconsideration of the Petition Decision and removal of the finality of the Office Action mailed October 18, 2006, are respectfully requested. Any fee for filing this request for reconsideration or in connection with this application during its pendency can be charged to Deposit Account No. 06-1050.

Respectfully submitted,
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By: _____

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